K070488

SEP - 4 2008

510(k) Summary
(as required by 21 CFR 807.92)

1. Submitter Information

Company Name:	MiCardia Corporation
Company Address:	30 Hughes – Suite 206 Irvine, CA 92618
Company Phone: Company Facsimile:	949-951-4888 949-951-4812
Contact Person:	Jeffrey P. DuMontelle Director of RA, QA and Compliance
Date Summary Prepared:	February 16, 2007

2. Device Identification

Trade or Proprietary Name:

Annuloplasty Band DR™ (Model RNG6)
Annuloplasty Ring DR™ (Model RNG7)

Common Name:	Ring, Annuloplasty
Classification:	Class II
Regulation Number:	21 CFR 870.3800
Product Code:	(74) KRH

3. Identification of Predicate Device

Device	Model #	FDA Clearance
CG Future®	638B/638R	K011395/K052860

4. General Description

MiCardia's Annuloplasty Band DR™ (Model RNG6) and Annuloplasty Ring DR™ (Model RNG7) function as annular support for the mitral annulus only. The devices are fabricated from a nickel titanium support ring surrounded by silicone with a polyester fabric covering. The devices are mounted on holders, packaged in a barrier packaging system and gamma sterilized. The devices are available in sizes 28 mm, 30 mm, 32 mm, 34 mm, and 36 mm. The size of the device is based on the inter-commissural markers placed on the ring. The devices are permanently implanted using sutures and typical surgical techniques for mitral valve repair using open-heart bypass.

The Annuloplasty Band DR™ and Annuloplasty Ring DR™ are used with associated accessories that include a holder, and reusable sizers (Model SZR1) and reusable handle (Model HNDL). The handle may be attached to either the sizers or the holders to aid in sizing or implantation. The diseased mitral valve annulus is measured with the appropriate MiCardia sizer. The sizers are provided in five (5) sizes; 28 mm, 30 mm, 32 mm, 34 mm, and 36 mm. The sizers are used to evaluate the distance between the patient's mitral valve commissures, anterior leaflet length and surface area, in order to select the appropriate size of annuloplasty band or ring for the repair. The appropriately sized band or ring is implanted using a series of sutures, typically 2-0 or 3-0, placed approximately 4 mm apart. The band or

ring is used to reduce the mitral annulus opening thereby causing a closer approximation of the anterior and posterior leaflets. This typically creates an increase in the depth of coaptation between the anterior and posterior leaflets when they are closed and resolves the pathological mitral valve (e.g. mitral regurgitation).

5. Intended Use

The Annuloplasty Band DR and Annuloplasty Ring DR devices are indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

6. Comparison of Required Technological Characteristics

MiCardia Corporation considers the Annuloplasty Band DR and Annuloplasty Ring DR to be substantially equivalent in technological characteristics (e.g. design and materials) and intended use to the predicate devices. Table 6.1 below is a comparison of the equivalency characteristics between the MiCardia Annuloplasty Band DR/Annuloplasty Ring DR and the predicate devices.

Characteristic	Equivalency
1. Product Labeling	Substantially equivalent
2. Intended Use	Identical
3. Physical Characteristics	Substantially equivalent
4. Anatomical Sites	Identical
5. Target Population	Substantially equivalent
6. Performance Testing	Substantially equivalent
7. Safety Characteristics	Substantially equivalent

Table 6.1

Characteristic Comparison of Annuloplasty Band DR/Ring DR to Predicate Devices

7. Summary of Non-Clinical Tests

The following was conducted;

a. Biocompatibility Testing
b. Computational Structural Analysis
c. Ring Tensile Strength
d. Suture Pull-out Strength
e. Sterilization Validation
f. Bioburden and Pyrogen
g. Packaging and Shelf Life Analysis
h. Corrosion
i. Magnetic Resonance Imaging Analysis

7. Conclusion

MiCardia Corporation has demonstrated that the Annuloplasty Band DR™ and Annuloplasty Ring DR™ are safe and effective for the intended use. The Annuloplasty Band DR and Annuloplasty Ring DR are substantially equivalent to the predicate devices with respect to their intended use and technological characteristics.

END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2008

MiCardia Corporation
c/o Mr. Jeffrey DuMontelle
Director of RA, QA and Compliance
30 Hughes Suite 206
Irvine CA 92618

Re: K070488
Trade/Device Name: MiCardia's Annuloplasty Band DR™ (Model RNG6) and Annuloplasty Ring DR™ (Model RNG7)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: May 22, 2008
Received: May 23, 2008

Dear Mr. DuMontelle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070488

Device Name: Annuloplasty Band DR/Annuloplasty Ring DR

Indications for Use:

The Annuloplasty Band DR and Annuloplasty Ring DR are indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070488

(Posted November 13, 2003)